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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/815,362	03/21/2001	Ken Chow	17243CIP3(AP)	4078
7590	02/10/2004		EXAMINER	
Carlos A. Fisher ALLERGAN, INC. T2-2E 2525 Dupont Drive Irvine, CA 92623			ANDERSON, REBECCA L	
			ART UNIT	PAPER NUMBER
			1626	

DATE MAILED: 02/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/815,362	Applicant(s) CHOW ET AL.	
	Examiner Rebecca L Anderson	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-108 is/are pending in the application.
 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☒ Claim(s) 108 is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☒ Claim(s) 1-4, 7-15, 20, 21, 26, 38, 46, 50-55, 71, 89, 97, 101, 103 and 104 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>1-108</u> | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims withdrawn from consideration are 5,6,16-19,22-25,27-37,39-45,47-49,56-70,72-88,90-96,98-100,102 and 105-107.

DETAILED ACTION

Claims 1-108 are currently pending in the instant application. Claim 108 is appears allowable over the prior art of record. Claims 1-4, 7-15, 20, 21, 26, 38, 46, 50-55, 71, 89, 97, 101, 103 and 104 are objected to as containing non-elected subject matter. Claims 5, 6, 16-19, 22-25, 27-37, 39-45, 47-49, 56-70, 72-88, 90-96, 98-100, 102 and 105-107 are withdrawn from consideration as being drawn to non-elected subject matter.

Inventorship

In view of the papers filed 13 November 2003, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(a). The inventorship of this application has been changed by adding Todd M. Heidelbaugh as a joint inventor.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of the file jacket and PTO PALM data to reflect the inventorship as corrected.

Election/Restrictions

In applicants response to the Office Action of 12 February 2003, received 11 August 2003, applicants representative argues that the Office did not make a restriction requirement in the Office Action of November 6, 2002, but the office made an election of species requirement. Applicants representative also argues that the examiner also formulated her own "generic claim" of which applicants representative asserts the

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applicant has not had a chance to accept or object and withdrawn all claims not encompassed by this "generic claim".

It is noted that the Office Action dated November 6, 2002 stated that:

Claims1 is generic to a plurality of disclosed patentably distinct species comprising for example, the compound of (1) example E-1 page 89, (2) C-2 page 89, (3) J-2 page 90, (4) C-6 page 91, (5) B-6 page 95 (6) K-3 page 98, etc. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

The Office Action dated November 6, 2002 also stated that:

Applicant is advised that the reply to this requirement to be complete must include an election of a single disclosed species even though the requirement be traversed. Upon election of a single disclosed species, a generic concept inclusive of the elected species will be identified by the Examiner for examination along with the elected species.

Therefore, the Office Action dated November 6, 2002 , as stated in the first paragraph of the action, did include a restriction requirement under 35 USC 121. It is also noted that an election of species is considered a restriction as can be seen by section 802.02 of the MPEP:

Restriction, a generic term, includes the practice of requiring an election between distinct inventions, for example, election between combination and subcombination inventions, and the practice relating to an election between independent inventions, for example, and election of species.

In the Office Action of 12 February 2003, the examiner formulated a generic concept, which followed the statement of the Office Action of 6 November 2002 which disclosed that upon the election of a single disclosed species, a generic concept inclusive of the elected species will be identified by the Examiner for examination along with the elected species. In the Office Action dated 12 February 2003, the Office reviewed the claims and disclosure to determine the scope of the independent invention

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encompassing the elected invention (generic concept) and proceeded the search and examination of same. The restriction requirement which states the elected invention (generic concept) of the Office Action dated 12 February 2003 was not made final in that action, thereby giving applicant an opportunity to accept or object to the elected invention identified as the generic concept.

Accordingly, as stated in the previous Office Action,

The elected compound has resulted in the following invention (generic concept), class 548 subclass 335.1, for search and examination:

The elected and examined invention is the compound as found in claim 1 wherein:

x is 1 or 2;

R₁ is independently selected from the group consisting of H; halogen; C₁₋₄alkyl; C₁₋₄alkenyl; C₁₋₄alkynyl; --COR₄ where **R₄** is H, C₁₋₄alkyl or C₁₋₄alkoxy; C₃₋₆cycloalkyl; aryl, cyano, nitro; trihalomethyl; oxo; or -(CH₂)_n-X-(CH₂)_m-(R₅)_o where **X** is O, S or N, **n** is 0-3, **m** is 0-3, **o** is 0-1, and **R₅** is methyl or H₁₋₂;

R₂ and **R₃** together consist of a partly saturated ring structure containing one double bond, wherein the double bond is shared with the ring including Y, having the formula -(C(R₆)_p)_q-X_s-(C(R₆)_p)_r-X_t-(C(R₆)_p)_u where each **R₆** is independently selected from the group consisting of H; halogen; C₁₋₄alkyl; C₁₋₄alkenyl; C₁₋₄alkynyl; --COR₄ where **R₄** is H, C₁₋₄alkyl or C₁₋₄alkoxy; C₃₋₆cycloalkyl; aryl; cyano; nitro; trihalomethyl and oxo where each **p** is independently 1 or 2; **q** is 0-4, **r** is 0-4, **u** is 0-4; each **X** is independently O, S or N and **s** is 0; **t** is 0; provided that q + r + u + s + t is 4;

and the ring including Y is a cyclohexane ring containing one double bond which is shared with the ring formed by R2 and R3 (a cyclohexane ring containing one double bond which is shared with the ring formed by R2 and R3 defines Y as $(C(R_7)_z)_s$ wherein each R7 is independently as previously defined for R1 above, each z is independently 1-2 and s is 1).

The remaining subject matter of claims 1-4, 7-15, 20, 21, 26, 38, 46, 50-55, 71, 89, 97, 101, 103 and 104 and the subject matter of claims 5, 6, 16-19, 22-25, 27-37, 39-45, 47-49, 56-70, 72-88, 90-96, 98-100, 102 and 105-107 stands withdrawn, 37 CFR 1.142(b), as being for non-elected inventions. The remaining compounds which are not within the elected invention, which are independent and distinct from the elected invention as they differ materially and structurally in composition and element, do not have unity with the elected compounds and therefore are withdrawn by means of a restriction requirement within the claims are, for example, the compounds of the formula as found in claim 1 wherein R1 is independently selected from the group consisting of $-COR_4$ wherein R4 is heteroaryl, wherein R2 and R3 are independently selected from the group consisting of H, halogen, C1-4alkyl, C1-4alkenyl, C1-4 alkynyl, $-COR_4$, wherein R2 and R3 together consist of a saturated, partly saturated, or unsaturated ring structure having the formula $-(C(R_6)_p)_q-X_s-(C(R_6)_p)_r-X_t-(C(R_6)_p)_u$ where each R6 is $-COR_4$ wherein R4 is heteroaryl and X is independently O, S or N and s and t are zero, wherein each R6 is independently selected from the group consisting of H; halogen; C1-4alkyl; C1-4alkenyl; C1-4alkynyl; $--COR_4$ where R4 is H, C1-4 alkyl or C1-4 alkoxy; C3-6cycloalkyl; aryl; cyano; nitro; trihalomethyl and oxo where each p is independently 1 or

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2; q is 0-5, r is 0-5, u is 0-5; each X is independently O, S or N and s is 1 or wherein Y is O, S or N, Y1CH₂, -CH=CH- or -CH=. Examples of specific compounds which are withdrawn are, for example, the compound of claim 25 which contains a piperidine ring, the compound of claim 85 which contains a hydrogenated quinoline, etc.

The above mentioned withdrawn compounds which are withdrawn from consideration as being for non-elected subject matter differ materially in structure and composition from the elected invention. The withdrawn compounds differ from those of the elected invention by, for example, by a piperidine, and a quinoline, which are chemically recognized to differ in structure and function. This recognized chemical diversity of the functional groups can be seen by the various classification of the products in the U.S. classification system, i.e. class 546 subclass 134 (quinoline) and class 546 subclass 184 (piperidine).

Therefore, again, the compounds which are withdrawn from consideration as being for non-elected subject matter differ materially in structure and composition and have been restricted properly as a reference which anticipated but the elected subject matter would not even render obvious the non-elected subject matter. Nowhere do applicants argue to the contrary. Nowhere do applicants point out and give reasons why the claims do not involve independent or distinct subject matter. These withdrawn compounds are independent and distinct from the elected invention and do not have unity with the elected compound and are therefore withdrawn by means of a restriction requirement within the claims under 35 USC 121. Under 35 USC 121, the claims may be restricted and the examination limited to a restricted invention.

Accordingly, the claims are drawn to more than a single invention and restriction as has been required is proper, 37 CFR 1.142(a) and is therefor made FINAL.

Claim Objections

Claims 1-4, 7-15, 20, 21, 26, 38, 46, 50-55, 71, 89, 97, 101, 103 and 104 are objected to as containing non-elected subject matter. The claims presented drawn solely to the elected subject matter as indicated supra would appear allowable over the prior art of record.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (703) 605-1157. Mrs. Anderson can normally be reached Monday through Friday 5:30am-2:00pm.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph McKane, can be reached at (703) 30804537.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone numbers are (703) 308-1235 and (703) 308-0196.

A facsimile center has been established. The hours of operation are Monday through Friday, 8:45am-4:45pm. The telecopier number for accessing the facsimile machine is (703) 872-9306.



Rebecca Anderson
Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1600



Joseph McKane
Supervisory Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1600